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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,718	03/15/2001	Howard M. Johnson	UF-10164R	5517

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BEUSSE BROWNLEE WOLTER MORA & MAIRE
390 N. ORANGE AVENUE
SUITE 2500
ORLANDO, FL 32801

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/808,718	JOHNSON ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,11-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8, 11-17 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 11/18/04 is acknowledged.

Claims 1-6, 8, 11-17 and 19-26 are pending.

2. In view of the papers filed 12/27/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by including an additional inventor Amy C. Hobeika.

The correct inventorship in the instant application is as follows: Howar Johnson; Barbara Torres, Scott Kominsky and Amy C. Hobeika.

In view of the amendment, filed 11/18/04 the following rejections remain:

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 8 and 11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action, mailed 07/13/04. **This is a New Matter rejection.**

Applicant's arguments filed on 11/18/04 have been fully considered but they are not persuasive.

Applicant asserts that because the phrase "prior melanoma development" is a logical and legitimate rephrasing of the language in the application as filed.

Contrary to Applicant as was stated in the previous Office Action the phrase " prior to melanoma development," claimed in claim 1, line 3 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for the "prior to melanoma development,". The specification and the claims as originally field only support "A method for achieving superantigen mediated expansion of antigen-specific T cells for inducing an immune response against melanoma which comprises administering a melanoma..."

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 9, 11, and 14-17 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kominsky et al. (2000, IDS) for the same reasons set forth in the previous Office Action, mailed 07/13/04.

Applicant's arguments filed on 11/18/04 have been fully considered but they are not persuasive.

Applicant asserts that he will provide a declaration of Dr. Johnson which will establish that the work provided in the Kaminski et al reference represent work derived from himself and other inventors of the present application.

It is noted however, that Applicant has not provided said declaration, thus rejection is maintained until such declaration is submitted.

7. Claims 1-6, 8, 11-17 and 19-26 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/26747 (1998, IDS) for the same reasons set forth in the previous Office Action, mailed 01/16/04.

Applicant's arguments filed on 05/20/04 and 07/01/04 have been fully considered but they are not persuasive.

Applicant asserts that: (i) '747 publication fail to teach an in vivo administration regimen that involves the *in vivo* administration of an antigen followed by the *in vivo* administration of a superantigen at an optimized time interval; (ii) '747 teaches that anergy can be achieved by delay of administration of a superantigen six days after administration of an antigen. Thus the '747 wholly misses the importance of the delay of the administeration of a superantigen to achieve the immune response.
Contrary to Applicant's assertion, as was stated in the previous Office Action, WO '747 teaches a method for achieving superantigen mediated expansion of antigen-specific T cells for cancer treatment/prophylaxis which comprises administering a tumor specific antigen composition, including melanoma specific antigen followed by administration of a superantigen (SEA/SEB) composition at an optimized time interval following said administering of said tumor specific antigen composition to maximize the cellular immune response to said antigen (see particularly pages, 2, 18-19 and pages 6 (superantigens) and 8 (tumor antigens). WO' 747 explicitly teaches that the present invention relates to the discovery that the clinical effects of an activated T cell in response to tumor antigen is exceeds when tumor antigen administered following by superantigen administration. Moreover, Applicant's attention is respectively drawn to page 19. W0'747 explicitly teaches that superantigens and antigen may be separately **administrated to a patient.** When the superantigen and antigens are administered separately, the time between administration may be anywhere in the range of from minutes to up about a weeks , varying in accordance with the specific disease and the specific combination of the therapeutic agents. It is the Examiner position that one skill in the art at the time the invention was made would interpret said phrase as that WO '747 teaches *in vivo* administration of antigen and superantigen at an optimized time interval.

Selected superantigens are capable of massively activating certain T-cell with defined TCR expression(see page 20 in particular). Clearly, contrary to Applicant's assertion, WO'707 teaches that the method of the invention can be used to induced T cellular immune response, not anergy, for cancer treatment, including melanoma development (see pages 7 –8, and 77 in particular). This is further evidenced by the fact that WO'747 directly teachers the ways of preventing the anergy, when using the methods of the invention (see overlapping pages 73 and 74 in particular). In addition, contrary to Applicants assertion, WO'747 clearly stated that the method of the invention can be used for tumor vaccination (see page 69 in particular). Clearly, WO'747 contemplated a method of administering a superantigen for the purpose of preventing the onset of tumor development. Thus is clear that both the prior art and applicant administer the same treatment, i.e. administration of melanoma specific antigen followed by administration of a superantigen composition at a optimized time interval, to the same patients to achieve the same results, i.e. expansion of antigen-specific T cell and delaying the onset of tumor development.

The reference clearly anticipates the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 6 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kominsky et al. (2000, IDS) for the same reasons set forth in the previous Office Action, mailed 07/13/04.

Applicant's arguments filed on 11/18/04 have been fully considered but they are not persuasive.

Applicant asserts that he will provide a declaration of Dr. Johnson which will establish that the work provided in the Kaminski et al reference represent work derived from himself and other inventors of the present application.

It is noted however, that Applicant has not provided said declaration, thus rejection is maintained until such declaration is submitted.

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
February 22, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600